

### **REMARKS**

Applicants respectfully request further examination and reconsideration in view of the above amendments and the arguments set forth fully below. In the Final Office Action mailed May 21, 2007, claims 1 and 3-19 have been rejected. In response, the Applicants have submitted the following remarks and amended claim 1. Accordingly, claims 1 and 3-19 are still pending. Favorable reconsideration is respectfully requested in view of the amended claims and the remarks below.

#### **Rejections Under 35 U.S.C. §103**

Claims 1, 3 and 6-7 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 4,136,690 to Anderson (hereinafter Anderson), in view of the European Heart Journal article by Kardys (hereinafter Kardys). The Applicants respectfully disagree with this rejection.

Anderson relates to vector analysis of ECG arrhythmias. The Anderson reference describes an invention that uses two ECG leads, but does not teach utilizing a three lead system, which renders the possibility of Anderson measuring a 3-D QRST angle impossible. It is stated within the Office Action that while Anderson does not teach defining a relationship between depolarization and repolarization, including measuring a 3-D QRS-T angle, Anderson does indeed teach calculating a variation between stored values of 2D QRST angles.

Within the Office Action, it is stated that Anderson further discloses that each stored 2-D QRS-T angle is tallied into one of a number of angular ranges for analysis and comparison between ranges, and the Examiner reads this as “calculating a variation between the successfully stored values.” The Examiner cites the Anderson reference, column 3, lines 56-57, column 7, lines 43-47 and column 8, lines 59-66. However, a close read of these Anderson citations indicates that there is neither an analysis, nor a calculation of any values in the Anderson reference, but rather a classification of each

consecutive stored value of the QRST angle. In other words, each value of the QRST angle is tallied into one of a number of angular ranges, and is preserved on a counter specific to the range. These continually updated counts on the counters maybe displayed, printed out, or plotted (Anderson, column 3, lines 58-64). There is no analysis or calculation occurring in the Anderson reference, merely classifying each stored value into an angular range and displaying the count of each range.

The Kardys reference is a study to assess the prognostic importance of the spatial QRS-T angle for fatal and non-fatal cardiac events. Kardys does not teach calculating a variation between the successfully stored values.

In contrast to the teachings of Anderson and Kardys, the present invention utilizes a 3-D QRS-T angle, which is more representative of true heart dye pole. The present invention utilizes three lead ECG systems in order to appropriately measure a 3-D QRST angle, which is something that is not obvious in light of Kardys and Anderson.

Further in contrast of the teachings of Anderson and Kardys, the present invention describes and claims "calculating a variation between the first value and the second value." The Applicants point the Examiner to the discussion in the specification of the present application on page 5, paragraph 23 through page 7, paragraph 28. It is quite clear that the description in these sections of the present specification teach an analysis and calculation of a variation between the first value and the second value that is not present in either the Anderson or Kardys reference. The teachings of the present application, specifically the calculating step as claimed in claim 1, is clearly not taught in Anderson, as Anderson merely classifies each stored value according to an angular range. The Kardys reference does not teach any sort of analysis or calculating as described or claimed in the present invention.

The Applicants respectfully submit that the age of the cited references indicates a lack of some teaching or suggestion supporting the combination. The Anderson patent was filed on October 31, 1977. The Kardys reference was accepted for publication on March 12, 2003. **Even with the benefit of an accepted publication date that is 26 years later than Anderson, Kardys still does not include some teaching or suggestion**

**that the art taught in each reference can and should be combined.** In other words, there is no teaching or suggestion in either reference to make the combination made in the Office Action.

Furthermore, the Anderson patent issued on January 30, 1979, and the Kardys reference was published sometime in 2003, after March 12. The present application was filed on April 15, 2004, over a year after the Kardys reference was published. **The Applicants respectfully submit that if the combination of the cited references was obvious, as is stated in the Office Action, then it is probable that such a combination would have been made prior to the filing of the present application.** Therefore, the Applicants submit that this combination of references is indeed not obvious.

The amended independent claim 1 is directed to a method of using an electrocardiogram signal to assess a patient's cardiac vulnerability to sudden cardiac death by the method comprising determining a first value representative of a 3-D QRST angle for a first beat of the electrocardiogram signal; determining a second value representative of a 3-D QRST angle for a second beat of the electrocardiogram signal, wherein determining the first and second values defines a relationship between depolarization and repolarization; calculating a variation between the first value and the second value; and outputting said calculated variation to an output device. As discussed above, neither Anderson nor Kardys teach or make obvious the steps of calculating a variation between a first and second value representative of a 3-D QRST angle. For at least these reasons, the independent claim 1 is allowable over the teachings of Anderson, Kardys and their combination.

Claims 3 and 6-7 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson, Kardys and their combination. Accordingly, claims 3 and 6-7 are also allowable as being dependent upon an allowable base claim.

Claims 4-5 and 8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of U.S. Patent Application No. 2004/0220635 to Burnes (hereinafter Burnes). Claims 4-5 and 8 are dependent upon the independent claim 1. As discussed above, the

independent claim 1 is allowable over the teachings of Anderson and Kardys. Accordingly, claims 4-5 and 8 are also allowable as being dependent upon an allowable base claim.

Claims 9 is rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of U.S. Patent No. 4,732,157 to Kaplan et al. (hereinafter Kaplan). Claim 9 is dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson and Kardys. Accordingly, claim 9 is also allowable as being dependent upon an allowable base claim.

Claims 10 and 11 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of U.S. Patent No. 5,265,617 to Verrier et al. (hereinafter Verrier). Claims 10-11 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson. Accordingly, claims 10-11 are also allowable as being dependent upon an allowable base claim.

Claims 12 and 14-16 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys as applied to claim 1 above, and further in view of Ralph et al. (hereinafter Ralph). Claims 12 and 14-16 are dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson and Kardys. Accordingly, claims 12 and 14-16 are also allowable as being dependent upon an allowable base claim.

Claim 13 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys, and further in view of Ralph and Verrier. Claim 13 is dependent upon the independent claim 1. As discussed above, the independent claim 1 is allowable over the teachings of Anderson and Kardys. Accordingly, claim 13 is also allowable as being dependent upon an allowable base claim.

Claim 17 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys, and further in view of Ralph and Burnes. Claim 17 is dependent upon the independent claim 1. As discussed above, independent claim 1 is

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allowable over the teachings of Anderson and Kardys. Accordingly, claim 17 is also allowable as being dependent upon allowable base claim.

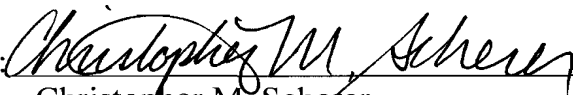
Claim 18 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys and Kaplan. Kaplan merely relates to an apparatus and method for quantifying variability and physiological wave forms, but like Anderson and Kardys, does not teach or make obvious calculating a variation between a first and second value of a 3D-QRST angle. Therefore, for the same reasons as discussed above with respect to claim 1, the Applicants respectfully submit that claim 18 is also allowable over the teachings of Anderson, Kardys, Kaplan and their combination.

Claim 19 has been rejected under 35 U.S.C. §103(a) as being unpatentable over Anderson in view of Kardys, and further in view of Kaplan and Verrier. Claim 19 is dependent upon independent claim 18. As discussed above, the independent claim 18 is allowable over the teachings of Anderson, Kardys, and Kaplan. Accordingly, Claim 19 is also allowable as being dependent upon an allowable base claim.

For these reason, Applicants respectfully submit that all claims are now in a condition for allowance, and allowance at an early date would be appreciated. Should the Examiner have any questions or comments, they are encouraged to call the undersigned at (414) 271-7590 to discuss the same that any outstanding issues may be expeditiously resolved.

Respectfully submitted,

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